

TRANSMITTAL FORM

EXPRESS MAIL NO.: EL953456281US

Application Serial Number	10/045,360
Filing Date	January 22, 2002
First Named Inventor	Whitehead
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket No.	UPA-008
BATCH NO. (after allowance)	Not applicable
Patent No.	Not applicable
Issue Date	Not applicable

ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application (PTO-1553)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences
<input type="checkbox"/> Amendment and Response <input type="checkbox"/> Preliminary Amendment <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets _____]	<input type="checkbox"/> Formal Drawing(s)	<input type="checkbox"/> Appeal Brief (in triplicate)
<input type="checkbox"/> Petition for Extension of Time	<input type="checkbox"/> Request For Continued Examination (RCE) Transmittal	<input type="checkbox"/> Status Inquiry
<input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations	<input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)	<input checked="" type="checkbox"/> Return Receipt Postcard
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8
<input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application	<input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8
	<input type="checkbox"/> Small Entity Statement	<input type="checkbox"/> Additional Enclosure(s) (please identify below)
	<input type="checkbox"/> CD(s) for large table or computer program	
	<input type="checkbox"/> Amendment After Allowance	
	<input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	

CORRESPONDENCE ADDRESS

Direct all correspondence to: Patent Administrator
Testa, Hurwitz & Thibault, LLP
High Street Tower
125 High Street
Boston, MA 02110
Tel. No.: (617) 248-7000
Fax No.: (617) 248-7100

SIGNATURE BLOCK

Respectfully submitted,

Date: March 14, 2002
Reg. No. 43,153
Tel. No.: (617) 248-7103
Fax No.: (617) 248-7100

Diana M. Steel
Attorney for Applicant
Testa, Hurwitz & Thibault, LLP
High Street Tower
125 High Street
Boston, MA 02110



EXPRESS MAIL MAILING LABEL NO.: EL953456281US

PATENT

Attorney Docket No: UPA-008
(8261/9)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Whitehead
SERIAL NO.: 10/045,360 GROUP NO.: Not yet assigned
FILED: January 22, 2002 EXAMINER: Not yet assigned
TITLE: METHODS FOR DETERMINING STEROID RESPONSIVENESS

Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Respectfully submitted,



Diana M. Steel
Attorney for Applicant
Testa, Hurwitz, & Thibeault, LLP
High Street Tower
125 High Street
Boston, Massachusetts 02110

Date: March 14, 2002
Reg. No. 43,153

Tel. No.: (617) 310-8168
Fax No.: (617) 248-7100



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FORM PTO - 1449 INFORMATION DISCLOSURE STATEMENT				ATTORNEY DOCKET NO.: UPA-008 APPLICANT: Whitehead SERIAL NO.: 10/045,360 FILING DATE: January 22, 2002 GROUP: Not yet assigned					
U.S. PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME		CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
FOREIGN PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
OTHER ART, JOURNAL ARTICLES, ETC.									
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)								
	C1	Butler et al., "Structure of the Mouse Serum Amyloid A 5 (SAA5) Gene: Relationship to Other Members of the Serum Amyloid A Family", Scand. J. Immunol., Vol. 45, pp. 160-165, 1997.							
	C2	Butler et al., "Mapping of the Mouse Serum Amyloid A Gene Cluster by Long-Range Polymerase Chain Reaction", Immunogenetics, Vol. 44, pp. 468-474, 1996.							
	C3	Cohen et al., "Therapy of Relapsing Multiple Sclerosis. Treatment Approaches for Nonresponders", J. Neuroimmunol., Vol. 98, pp. 29-36, 1999.							
	C4	Cunnane et al., "Amyloid Precursors and Amyloidosis in Rheumatoid Arthritis", Bailliére's Clinical Rheumatol., Vol. 13, No. 4, pp. 615-628, 1999.							
	C5	Cunnane et al., "Serum Amyloid A in the Assessment of Early Inflammatory Arthritis", Rheumatol., 27:1, 2000.							
	C6	Gaughan et al., "Ribozyme Mediated Cleavage of Acute Phase Serum Amyloid A (A-SAA) mRNA in Vitro", FEBS Letters, 374, pp. 241-245, 1995.							
	C7	Gaughan et al., "Efficient In Vitro Cleavage of Mouse Acute Phase Serum Amyloid A mRNA Mediated by a Synthetic Hammerhead Ribozyme", Scand. J. Immunol., Vol. 46, pp. 51-58, 1997.							
	C8	Grehan et al., "Expression of a Biologically Active Recombinant Mouse IL-1 Receptor Antagonist and its Use in Vivo to Modulate Aspects of the Acute Phase Response", J. Immunol., pp. 369-378, 1997.							
	C9	Grehan et al., "Down-Regulation of the Major Circulating Precursors of Proteins Deposited in Secondary Amyloidosis by a Recombinant Mouse Interleukin-1 Receptor Antagonist", Eur. J. Immunol., Vol. 27, pp. 2593-2599, 1997.							


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INFORMATION DISCLOSURE STATEMENT
ATTORNEY DOCKET NO.: UPA-008


APPLICANT: Whitehead

SERIAL NO.: 10/045,360

FILING DATE: January 22, 2002

GROUP: Not yet assigned

C10	Hanauer et al., "Management of Crohn's Disease in Adults", Amer. J. Gastroenter., Vol. 92, No. 4, 1997.
C11	Hendrickse et al., "Rifampicin-Induced Non-Responsiveness to Corticosteroid Treatment in Nephrotic Syndrome", Brit. Med. J., p. 306, February 3, 1979.
C12	Jain et al., "Rifampicin Induced Non-Responsiveness to Steroids in Bronchial Asthma", Indian. J. Chest. Dis. & All Sci., Vol. 31, No. 4, pp. 271-274, 1989.
C13	Jensen et al., "Competitive Reverse Transcription Polymerase Chain Reaction for Quantifying Pre-mRNA and mRNA of Major Acute Phase Proteins", J. Immunol. Meth., Vol. 215, pp. 45-48, 1998.
C14	Jensen et al., "Review Article - Regulation of Serum Amyloid A Protein Expression During the Acute-Phase Response", Biochem. J., Vol. 334, pp. 489-503, 1998.
C15	Jensen et al., "Evolutionary Analyses and Acute Phase Response", J. Immunol., pp. 384-392, 1997.
C16	Jorgensen et al., "Serum Amyloid A Transcription in Atlantic Salmon (<i>Salmo salar</i> L.) Hepatocytes is enhanced by Stimulation with Macrophage Factors, Recombinant Human IL-1 β , IL-6 and TNF α or bacterial lipopolysaccharide", Devel. and Compar. Immunol., Vol. 24, pp. 553-563, 2000.
C17	Kornbluth et al., "Ulcerative Colitis Practice Guidelines in Adults", Am. J. of Gastroent., Vol. 92, No. 2, 1997.
C18	Longley et al., "Posttranscriptional Regulation of Acute Phase Serum Amyloid A2 Expression by the 5'- and 3' - Untranslated Regions of Its mRNA", J. Immunol., pp. 4538-4545, 1999.
C19	McCormack et al., "Generation of Soluble Recombinant Human Acute Phase Serum Amyloid A2 (A-SAA2) Protein and its Use in Development of a A-SAA Specific ELISA", J. Immunol. Meth., Vol. 198, pp. 101-110, 1996.
C20	O'Hara et al., "Acute-Phase Serum Amyloid A Production by Rheumatoid Arthritis Synovial Tissue", Arthritis Res. Vol. 2, pp. 142-144, 2000.
C21	O'Mahony et al., "Review Article: Management of Patients with Non-Responsive Coeliac Disease", Aliment Pharmacol. Ther., Vol. 10, pp. 671-68, 1996.
C22	Present, "How To Do Without Steroids in Inflammatory Bowel Disease", Inflamm. Bowel Dis., Vol. 6, No. 1, February 2000.
C23	Rebuck, "Asthma: Non-Responsiveness to Conventional Therapy", Eur. J. Respir. Dis., 69 (Suppl. 147), pp. 105-109, 1986.
C24	Rygg et al., "In Vitro Evaluation of an Enhanced Human Serum Amyloid A (SAA2) Promoter-Regulated Soluble TNF Receptor Fusion Protein for Anti-Inflammatory Gene Therapy", Scand. J. Immunol., Vol. 53, pp. 588-595, 2001.
C25	Spitz et al., "Response to the Antiprogesterone RU 486 (mifepristone) During Early Pregnancy and the Menstrual Cycle in Women", J. Reprod. Fert., Suppl., Vol. 37, pp. 253-260, 1989.

FORM PTO - 1449 INFORMATION DISCLOSURE STATEMENTS			ATTORNEY DOCKET NO.: UPA-008 APPLICANT: Whitehead SERIAL NO.: 10/045,360 FILING DATE: January 22, 2002 GROUP: Not yet assigned
	C26	Steel et al., "Expression and Regulation of Constitutive and Acute Phase Serum Amyloid A mRNAs in Hepatic and Non-Hepatic Cell Lines", Scand. J. Immunol., Vol. 44, pp. 493-500, 1996.	
	C27	Uhlar et al., "Wallaby Serum Amyloid A Protein: cDNA Cloning, Sequence and Evolutionary Analysis", Scand. J. Immunol., Vol. 43, pp. 271-276, 1996.	
	C28	Uhlar et al., "The Kinetics and Magnitude of the Synergistic Activation of the Serum Amyloid A Promoter by IL-1 β and IL-6 is Determined by the Order of Cytokine Addition", Scand. J. Immunol., Vol. 49, pp. 399-404, 1999.	
	C29	Uhlar et al., "Use of the Acute Phase Serum Amyloid A2 (SAA2) Gene Promoter in the Analysis of Pro- and Anti-Inflammatory Mediators: Differential Kinetics of SAA2 Promoter Induction by IL-1 β and TNF- α compared to IL-6", J. Immunol. Meth., Vol. 203, pp. 123-130, 1997.	
	C30	Uhlar et al., "Review Article - Serum Amyloid A, the Major Vertebrate Acute-Phase Reactant", Eur. J. Biochem., Vol. 265, pp. 501-523, 1999.	
EXAMINER			DATE CONSIDERED

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